K020170 1/1

Summary of Safety and Effectiveness

Encore Orthopedics®, Inc.
9800 Metric Blvd
Austin, TX 78758
512-832-9500

FEB 1 1 2002

Trade Name: Keystone® Hip System Calcar Replacement Body and Build-up

Common Name: Cementless hip stem

Classification Name: Hip joint metal/polymer/metal semi-constrained porous coated uncemented prosthesis

Description: The Keystone® Hip System is available in a variety of proximal bodies and distal stem diameter and length configurations. The proximal body and stem are attached via a Morse type taper junction with an axially loading screw providing secondary attachment. The bodies, stems, and fixation screws were cleared on 510(k) K000521. All components are manufactured from titanium alloy (Ti-6Al-4V) that conforms to ASTM F136 with a porous coating that conforms to ASTM 1854-98 applied to the proximal body.

The additional components that are the subject of this **Special 510(k)** submission are the calcar replacement bodies and calcar build-ups.

The calcar replacement bodies are to be used either with or without a calcar build-up. During revision surgery or treatment of intertrochanteric fractures, the medial calcar bone is often deficient. This implant allows the surgeon to rest the calcar platform of the stem on the remaining medial bone. The modular build-up is available in a +15 and +30mm height for each size stem. The build-up is attached to the stem using an attachment screw. The modular build-ups are fabricated from wrought titanium-aluminum-vanadium alloy (Ti-6Al-4V) conforming to ASTM F136.

The attachment screw is used to attach the calcar build-up to the calcar replacement bodies. The attachment screw is fabricated from wrought titanium-aluminum-vanadium alloy (Ti-6Al-4V) conforming to ASTM F136.

Intended Use: The Keystone® Hip System is intended for treatment of patients who are candidates for total hip arthroplasty because the natural femoral head and neck have been affected by osteoarthritis, inflammatory arthritis, traumatic arthritis, rheumatoid arthritis, avascular necrosis or femoral neck fracture, and revision arthroplasty.

Comparable Features to Predicate Device(s): Features comparable to predicate devices include same materials, design and indications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 1 2002

Ms. Joanna Droege
Regulatory/QA Engineer
Encore Medical Corporation
9800 Metric Boulevard
Austin, Texas 78758

Re: K020170
Trade Name: Keystone® Hip System Calar Replacement Body and Build-up
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: LPH
Dated: January 14, 2002
Received: January 17, 2002

Dear Ms. Droege:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Miriam C. Provost
for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K020170

510(k) Number (if known): _____

Device Name: Keystone® Hip System Calcar Replacement Body and Build-up

Indications For Use:

Keystone® Hip System
Indications For Use

The indications for use of the total hip replacement prosthesis include: noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis; rheumatoid arthritis; correction of functional deformity; revision procedures where other treatments or devices have failed; and treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement, which is unmanageable using other techniques. This stem is to be press-fit.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____
(per 21 CFR 801.109)

(Optional Format 1-2-96)_

OR II

Miriam C Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K020170

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